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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/000,052	11/01/2001	Kerry Bradley	A01P1055US01	9628
36802	7590	10/07/2004	EXAMINER	
PACESETTER, INC.			MULLEN, KRISTEN DROESCH	
15900 VALLEY VIEW COURT			ART UNIT	PAPER NUMBER
SYLMAR, CA 91392-9221			3762	4

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/000,052

Applicant(s)

BRADLEY, KERRY

Examiner

Kristen Mullen (formerly
Droesch)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/19/01 (Corr. Filing Rcpt).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 20-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 38-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: Apparatus and method including integration of cardiac depolarization or contraction information.

Species II: Apparatus and method including derivation of cardiac depolarization or contraction information.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 38, 44, 45, and 49 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Derrick Reed on 9/17/04 a provisional election was made without traverse to prosecute the invention of Species I, claims 1-19, and 38-51. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 14, it is unclear how the parameter can comprise a sample mean of historic integral values minus a product equal to a factor of 1 to 6 times a calculated deviation corresponding to the sample mean ***and also*** comprise a calculated deviation of historic integral values

Claim 14 recites the limitation "the statistical parameter" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-8, 10, 38-41, 43-45, 47-49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Lu et al. (5,391,192).

Regarding claim 1, 10, 38-39, and 43, Lu et al. shows a method and one or more computer readable media having computer readable instructions thereon which cause the stimulation device to execute the method steps of: stimulating heart tissue with stimulation energy (100); obtaining information related to at least one of cardiac depolarization and cardiac contraction (102), integrating or processing the information to provide a value (108); comparing the value with at least one parameter (118, 122), and implementing a capture technique in response to the comparing (Fig. 3; Col. 4, line 44-Col. 5, line 65) .

With respect to claim 44, Lu et al. shows a method comprising: obtaining information related to at least one of cardiac depolarization and cardiac contraction (102), processing the information to provide at least one integral value (108, 115), repeating the obtaining and the processing to provide a plurality of values, determining a parameter from the plurality of values, the parameter comprising a statistic (average) , obtaining

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additional information related to at least one of cardiac depolarization and cardiac contraction, processing the additional information to provide at least one additional value; comparing the at least one additional value to the parameter (118, 122, 126); and implementing a capture technique in response to the comparing (Fig. 3; Col. 4, line 44-Col. 5, line 65) .

Regarding claim 2, Lu et al. shows the step of obtaining comprises receiving sensor data from at least one sensor (18) positioned proximal to the heart.

With respect to claim 3, Lu et al. shows the step of integrating comprises integration of at least one of voltage and current information over a time interval (Fig. 2; Col. 4, lines 52-68)

Regarding claims 4-5, and 40-41, Lu et al. shows the parameter comprises a statistical parameter (average) based on historic information related to cardiac depolarization (Col. 5, lines 37-65).

With respect to claim 6, Lu et al. further shows the step of storing the value (115) (Fig. 3; Col. 4, line 44-Col. 5, line 65).

Regarding claim 7, Lu et al. shows repeating the obtaining, the integrating and the storing to store a plurality of values (Fig. 3; Col. 4, line 44-Col. 5, line 65).

With respect to claim 8, Lu et al. shows determining a statistical parameter of the plurality of values (Col. 5, lines 37-65).

Regarding claims 45 and 48, Lu et al. shows a cardiac stimulation device comprising a sensor (18) and a processor operably coupled to the sensor, the processor (12) being configured to determine a value from the information, the value comprising an integral value, and being configured to determine a parameter from the information, the

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parameter comprising a statistic (average), and the processor is configured to implement a capture technique (Fig. 3; Col. 4, line 44-Col. 5, line 65).

Regarding claims 47 and 51, Lu et al further shows the processor is configured to compare the value and the parameter and means for comparing the value and the parameter (122, 126) (Fig. 3; Col. 4, line 44-Col. 5, line 65).

With respect to claim 49, Lu et al. shows an implantable cardiac stimulation device comprising means (18) for obtaining information related to at least one of cardiac depolarization and cardiac contraction; and means (12) for determining a value from the information, the value comprising an integral value, and determining a parameter from the information, the parameter comprising a statistic (average) (Fig. 3; Col. 4, line 44-Col. 5, line 65).

7. Claims 1-3, 10-11, 16-17, 19, 38-39, 43, 45, and 48-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Poore et al (6,731,985).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, 10, 11, 19, 38-39, and 43, Poore et al. shows a method and one or more computer readable media having computer readable instructions thereon which cause the stimulation device to execute the method steps of: stimulating heart tissue with stimulation energy; obtaining information related to at least one of cardiac

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depolarization and cardiac contraction, integrating or processing the information to provide a value; comparing the value with at least one parameter, and implementing one of a capture technique or fusion avoidance technique in response to the comparing (Fig. 7; Col. 15, lines 10-61).

With respect to claim 2, Poore et al. shows the step of obtaining comprises receiving sensor data from at least one sensor positioned proximal to the heart (Col. 15, lines 10-61).

Regarding claim 3, Poore et al. shows the step of integrating comprises integration of at least one of voltage and current information over a time interval (Fig .6)

With respect to claim 6, Poore et al. further shows the step of storing the value (Col. 10, lines 5-9).

Regarding claims 16-17, Poore et al. shows the integral comprises an integral starting at cardiac depolarization and ending at a baseline potential (Fig .6)

Regarding claims 45 and 48, Poore et al. shows a cardiac stimulation device comprising a sensor and a processor operably coupled to the sensor, the processor being configured to determine a value from the information, the value comprising an integral value, and being configured to determine a parameter from the information, the parameter comprising a statistic (average, Standard deviation coefficient of variation), and the processor is configured to implement a capture technique or fusion avoidance technique (Fig. 2; Col. 10, lines 5-9).

With respect to claim 49, Lu et al. shows an implantable cardiac stimulation device comprising means (18) for obtaining information related to at least one of cardiac depolarization and cardiac contraction; and means (12) for determining a value from the

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information, the value comprising an integral value, and determining a parameter from the information, the parameter comprising a statistic (average, Standard deviation coefficient of variation) (Fig. 3; Col. 4, line 44-Col. 5, line 65).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 9, 42, 46 and 50 are rejected under 35 U.S.C. 103(a) as being obvious over Lu et al. (5,391,192). Lu et al. discloses the claimed invention except for the parameter corresponding to a probability. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to utilize a probability for the parameter, since applicant has not disclosed that this probability parameter provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any parameter such as the parameter based on the average taught by Lu et al.

10. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poore et al (6,731,985). Poore et al. discloses the claimed invention except for the parameter comprising a sample mean of historic integral values minus a product, the product equal to a factor times a calculated deviation corresponding to the sample mean; the factor comprising a number between 1 and 6; and the statistical parameter comprising a calculated deviation of historic integral values. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to utilize a

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parameter comprising a sample mean of historic integral values minus a product, the product equal to a factor times a calculated deviation corresponding to the sample mean; the factor comprising a number between 1 and 6; and the statistical parameter comprising a calculated deviation of historic integral values, since applicant has not disclosed that these particular parameters provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any parameter such as the parameter based on a predetermined value taught by Poore et al.

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poore et al (6,731,985) in view of Obel (5,836,984). Poore et al. is as explained before. Although Poore et al fails to teach the fusion avoidance technique comprises pulse inhibition, attention is directed to Obel which teaches inhibiting the application of pulses in order to avoid fusion, avoid excessive energy in the stimulation pulses and improve the longevity of the battery (Col. 1, lines 19-25; Col. 2, lines 29-31). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to incorporate the method of pulse inhibition as taught by Obel in the Poore et al. method in order to avoid fusion, avoid excessive energy in the stimulation pulses and improve the longevity of the battery.

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being obvious over Poore et al (6,731,985). Poore et al. discloses the claimed invention except for the parameter corresponding to a probability. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to utilize a probability for the parameter, since applicant has not disclosed that this probability parameter provides any criticality and /or unexpected results and it appears that the invention would perform

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equally well with any parameter such as the parameter based on a predetermined value taught by Poore et al.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Conclusion

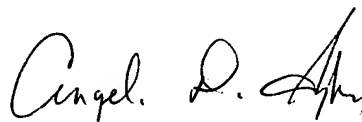
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30 am-6:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDM



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700